FEB 2 4 2010

K093181

510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
PK® Button Electrode

General Information

Manufacturer:	Gyrus Medical Ltd Fortran Road, St Mellons Cardiff, CF3 0LT, UK
Establishment Registration Number:	9617070
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Graham A. L. Baillie Senior Regulatory Specialist
Date Prepared:	October 6 2009

Device Description

Classification Name:	Endoscopic Electrosurgical Unit and Accessories Class 2 21 CFR 876.4300 Gastroenterology-Urology Panel
Project Name:	Gyrus ACMI PK® Button Electrode
Trade Name(s):	Bipolar Vaporization and Coagulation Electrode
Generic/Common Name:	Electrosurgical vaporization and coagulation device

Predicate Devices

SuperSect® & SuperLoop® Electrodes, Gyrus PlasmaKinetic™ SuperPulse® System	K031085
The Gyrus (ACMI) Endourology System	K990628
The Circon ACMI USA Elite System ™ Vaporization Electrode and VaporTome™ Resection Electrode	K973820
Olympus TURis Button (Resectoscope loops)	K903323

Intended Use

The Gyrus ACMI PK® Button Electrode is a bipolar instrument intended for use in urological surgical procedures involving the ablation or removal of soft tissue and where associated hemostasis is required. The specific urological indication for the PK® Button is transurethral electrovaporization of the prostate (TUVP/TVP) for benign prostatic hypertrophy only. The PK® Button is not to be used to resect tissue.

Product Description

The proposed PK® Button is a bipolar, sterile/disposable, vaporizing/coagulating electrode) that uses the same Gyrus ACMI PlasmaKinetic™ (PK®) SuperPulse® Generator and footswitch, as the predicate bipolar Plasma V vaporizing/coagulating electrode.The PK® Button is a Front Loading Urological Instrument Device (FLUID) that will be front loaded into the reusable Elite USA 1 and 2 resectoscope (cleared under K021166).
The purpose of this submission is to demonstrate equivalence to predicate vaporizing/coagulating electrodes and clear the PK® Button electrode for a TUVP indication.

Technological Characteristics and Substantial Equivalence

The PK® Button utilizes features incorporated into the following legally marketed predicate devices:

- The bipolar PK® Button Electrode connects to the same electrosurgical generator as the predicate Plasma V vaporizing electrode (K990628) and the SuperSect® and SuperLoop® bipolar FLUID electrodes (K031085). Similar to the predicate Plasma V electrode and SuperSect® and SuperLoop, an identification capacitor imbedded in the single use connector cable will be recognized by the generator to set default optimal power output parameters for the subject instrument.
- The distal tip of the proposed PK® Button electrode has the same button design and uses the same materials as the predicate Olympus TURis Button electrode, (K903323).

Continued... Technological Characteristics and Substantial Equivalence

- The PK® Button uses the same patient-contacting materials that are utilized in the predicate devices, as well as other legally marketed devices manufactured by Gyrus ACMI.
- The PK® Button will have the same intended use and similar indications as the predicate Gyrus ACMI USA Elite System™ VaporTrode™ Vaporization Electrode that includes: "*... coagulation and vaporization of soft tissue, including prostatic and bladder tissue and the treatment of benign prostatic hyperplasia...*"

The bipolar vaporization and coagulation performance of the PK® Button were compared against the known tissue vaporization and coagulation performance characteristics of the predicate Plasma V and TURis Button electrodes. Bench and animal testing demonstrated that the performance requirements were met, and that the PK® Button exhibited comparable performance characteristics to both predicates.

In summary, the PK® Button electrode is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6(
Silver Spring, MD 20993-0002

Mr. Graham A.L. Baillie
Senior Regulatory Specialist
Gyrus ACMI, Inc.
136 Turnpike Road
SOUTHBOROUGH MA 01772

FEB 2 4 2010

Re: K093181
Trade/Device Name: Gyrus ACMI PK® Button Electrode
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FAS
Dated: February 2, 2010
Received: February 3, 2010

Dear Mr. Baillie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

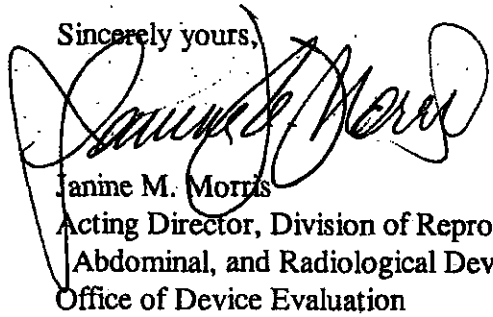
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K093181

Device Name: Gyrus ACMI PK® Button Electrode

Indications for Use:

The Gyrus ACMI PK® Button Electrode is a bipolar instrument intended for use in urological surgical procedures involving the ablation or removal of soft tissue and where associated hemostasis is required. The specific urological indication for the PK® Button is transurethral electrovaporization of the prostate (TUVP/TVP) for benign prostatic hypertrophy only. The PK® Button is not to be used to resect tissue.

Prescription Use: __ **X** __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K093181